Table 1: Deficiencies identified by EPA in its June 22, 2012 Cover Letter:

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1	*"The discussion of the process used to evaluate risks to humans and the conclusions were not clearly presented and, in fact, there were several instances of incorrect or misleading information. For example, the BHHRA repeatedly stated that the exposure assessment assumed someone ate fish every day of the year for 30 years.* *The LWG is fully aware that such a statement is not accurate. Consumption rates are average lifetime intake doses mathematically averaged to give an average daily rate. EPA commented on this issue in our February 9, 2010 comment letter[1]; however, the LWG failed to address it."*	This issue was not raised by EPA during development and finalization of the Programmatic Work Plan.	On July 16, 2010, EPA provided five specific comments on text in the BHHRA (**comments S91, S96, S143, S150, and S179, discussed below as 1.a through 1.d**). EPA identified only two of these comments as a "directed change."	LWG agreed to revise all text as requested.	All text revised or deleted as requested. One instance (§6.2.5.3) of this "every day of every year" formulation of the fish consumption rate was carried through into the May 2011 draft as an oversight. EPA did not comment on this specific sentence in the 2009 draft.	
1a			July 16, 2010, **comment S91** (revise): §5.2.5, pp. 86-91: "When discussing fish consumption in the Uncertainty Section, revise the text as indicated: *"Fish consumption was assumed to occur at this level every day of every year for 70 years (or 30 years)."* Fish ingestion rates are annually amortized based on the estimated number of fish meals per month and typical serving sizes. This rate does not imply that fish is ingested every day. In fact, all ingestion for a given rate could in theory occur over a few to several months, with no fish consumption for the rest of the year. In addition, such patterns could change over the course of 30 years, and greater fish consumption could occur in some years and less in others. The assumption is that over the course of 30 years, individual fish ingestion rates don't change substantively. This comment also applies to the discussion regarding consumption of shellfish on page 91.	LWG November 18, 2010 *General Responses to EPA's Non-Directive Comment Key Issues on the BHHRA*: "The BHHRA will be revised consistent with the comment."	Text modified consistent with the comment resolution.	
1b			July 16, 2010, **comment S96 b** (directed change): §5.2.6, pp. 91-92: "Uncertainties should be discussed in Section 7, Uncertainty Analysis. Move the last paragraph in this section to the uncertainty section Modify the following sentence: *"The shellfish consumption scenario assumes the same ingestion rate every day*	LWG September 15, 2010 *General Responses to Directed Comments on BHHRA*: "As discussed at the September 9 meeting, the BHHRA will be revised per these directed changes."	Text modified consistent with the comment resolution.	

[1] Note that EPA's February 9, 2010 letter does not discuss this issue; EPA's comments on average consumption rates are found in the July 16, 2010 BHHRA Specific Comments table.

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			of every year for 30 years." to note that, as stated in the comments above on fish consumption, shellfish consumption rates are annually amortized based on the estimated number of shellfish meals per month and typical serving sizes. This rate does not imply that the same amount of fish is consumed every day."			
1c			July 16, 2010, **comment S143,** §7.2.5.3, p. 121 (issue): Delete or modify this sentence as shown: "In addition to the uncertainties behind the rates of fish consumption, it was assumed that the frequency of consumption occurred at the same ingestion rate every day of every year for 30 years for the adult fisher scenarios." The reference to consuming fish or shellfish "every day of the year" is misleading, as the values for ingestion of fish and shellfish represent annualized rates. For example, the rate of 17.5 g/day is equivalent to two 8-oz meals per month. Using a daily rate is a method to simplify the risk calculations, and does not imply that fish and shellfish are consumed on a daily basis.	See comment resolution in 1a above.	"In addition to the uncertainties behind the rates of fish consumption, it was assumed that the frequency of consumption occurred at the same ingestion rate ~~every day of every year~~ for 30 years for the adult fisher scenarios."	
1d			July 16, 2010, **comment S150**, §7.2.5.3, p. 123 (directed change): Delete or revise the following sentence to clearly note that daily consumption rates represent mathematical artifacts to account for annual rates: *"Shellfish consumption was assumed to occur at the same rate every day of every year for 30 years."*	See comment resolution in 1b above.	~~"Shellfish consumption was assumed to occur at the same rate every day of every year for 30 years.~~ Daily shellfish consumption rates used in this BHHRA represent mathematical artifacts to account for annual consumption rates. The daily consumption rates for shellfish represent approximately two and a half 8-ounce meals per month (18 g/day ingestion rate), and just less than one 8-ounce meal every two months (3.3 g/day ingestion rate)."	
1e			July 16, 2010, **comment S179,** §8.1.1.1, pp. 138-139 (revise): Delete or revise the text in the third sentence and in all subsequent text in this section and Section 8.1.1.2 as indicated: *"Fish consumption was assumed to occur at the same ingestion rate, every day of every year"* The reference to consuming fish or shellfish "every day of the year" is misleading in that the fish and shellfish ingestion rates represent annual rates converted to average daily rates.	See comment resolution in 1a above.	"Fish consumption was assumed to occur at the same ingestion rate ~~, every day of every year,~~ for 30 years for an adult and for 6 years for a child." "Shellfish consumption was assumed to occur at the same ingestion rate~~, every day of every year,~~ for 30 years."	
2a	*"There were several instances where the BHHRA does not fully reflect EPA's directions for change, directions given years before and reiterated in our comments to previous versions.*	§3.4.3.1, p. 25-26. "Replicate composite samples were collected for each fishing zone for carp, crappie, and bullhead and at three of the eight river mile stations for bass. The replicate composite samples will be averaged	July 16, 2010, **comment S52** §3.4, p. 31 (clarify): "In this section and subsequently throughout the risk assessment, replace the term "95% UCL/max EPC" with "RME EPC." The repeated references to a "mean" EPC relative to one based on a 95 percent UCL	LWG November 18, 2010 *General Responses to EPA's Non-Directive Comment Key Issues on the BHHRA*: "The EPCs will be described in a factual manner in the BHHRA (i.e., the EPC will be identified as the mean, 95% UCL, or	Revised text §3.4. ~~"The EPCs used in this BHHRA incorporate CT and RME methods, consistent with EPA guidance. Because the RME scenarios in this BHHRA use either the maximum detected concentration or the 95% upper confidence limit (95% UCL) on the~~	"EPCs for RME evaluations represent either the 95 percent UCL, or the maximum detected value when either there was insufficient data to calculate a UCL or the calculated UCL was greater than the maximum reported

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	For example, EPA's February 2010[2] comment on Section 3.4, page 31 was: *"In this section and subsequently throughout the risk assessment, replace the term "95% UCL/max EPC" with "RME EPC." The repeated references to a "mean"* *EPC relative to one based on a 95 percent UCL or maximum concentration is misleading. The text in the second paragraph incorrectly states that exposure point concentrations would be calculated differently for central tendency (CTE) and reasonable maximum (RME) exposures. Consistent with EPA guidance (1992,2000), the EPC should represent an estimate of the arithmetic average concentration for a contaminant based on a set of site sampling data. Because of the uncertainty associated with estimating the true average concentration at a site, the 95 percent UCL of the arithmetic mean should be used for this variable. The 95 percent UCL provides reasonable confidence that the true site average will not be underestimated. The average concentration, defined as the 95 percent UCL, should be used for both CTE and RME evaluations. The RME evaluation should be distinguished from CTE by accounting for variability in such variables as exposure frequency and intake rates."* *However, the LWG did not make the change, claiming that the EPCs were described in a factual manner. Use of the term 95% UCL/Max Scenario is incorrect and needs to be changed throughout the document. RME*	and the arithmetic mean concentrations will be used as EPCs for individual sampling locations. To address potential variation in tissue concentrations, the maximum composite results for each fishing zone and at the three river mile segments will also be used as EPCs for individual sampling locations. The uncertainty associated with using the average and maximum concentrations as EPCs will be discussed in the risk assessment. At the one-mile river mile stations where replicate composite samples were not collected for bass, the results of the single composite sample will be used as EPCs for these stations. Site-wide tissue EPCs will also be estimated using mean concentrations and 95 percent upper confidence limit (UCL) on the average or maximum composite results. Where sufficient data are available, the 95% UCLs will be calculated using an approach agreed to by the LWG and EPA and its partners, and the 95% UCLs will be used as site-wide EPCs. If sufficient data are not available, the maximum composite results will be used as site-wide EPCs. In addition, the arithmetic mean of individual sampling location EPCs will be used as site-wide EPCs."	or maximum concentration is misleading. The text in the second paragraph incorrectly states that exposure point concentrations would be calculated differently for central tendency (CTE) and reasonable maximum (RME) exposures. Consistent with EPA guidance (1992, 2000), the EPC should represent an estimate of the arithmetic average concentration for a contaminant based on a set of site sampling data. Because of the uncertainty associated with estimating the true average concentration at a site, the 95 percent UCL of the arithmetic mean should be used for this variable. The 95 percent UCL provides reasonable confidence that the true site average will not be underestimated. The average concentration, defined as the 95 percent UCL, should be used for both CTE and RME evaluations. The RME evaluation should be distinguished from CTE by accounting for variability in such variables as exposure frequency and intake rates."	maximum). The terms RME and CT will not be used in reference to the EPCs." "EPA will not require the addition of beach user exposure to groundwater seeps, use of the 95% UCL/maximum concentration for all exposure scenarios, or new child receptors." EPA December 8, 2010 *EPA General Responses to EPA Non-Directed RI, BHHRA and BERA Comments*: "EPA has reviewed the LWG responses, as summarized in the tables, and has determined that the vast majority of issues associated with addressing EPA's comments have been resolved. However, there were three comments for which the LWG did not agree to make the specified changes." Includes three unrelated comments and additional unrelated clarifications.	~~arithmetic mean as the EPC for an exposure area, this BHHRA uses the term "95% UCL/max" to reference RME EPCs, and "mean" to reference CT EPCs.~~ EPCs were calculated for the 95% upper confidence limit on the arithmetic mean (95% UCL) and the arithmetic mean for each exposure area. In some exposure areas, the maximum concentration was used instead of the 95% UCL. Therefore, the EPCs are referred to as the 95% UCL/max and mean throughout this BHHRA."	value. Although inconsistent with EPA guidance (EPA 1992), EPCs for sediment and surface water CT evaluations were calculated as the simple arithmetic mean. EPCs for fish/shellfish consumption scenarios are the lesser of the 95 percent UCL or the maximum detected concentration, central tendency evaluations were achieved by using mean or median consumption rates."

[2] See note 1.

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	and CT are not defined based solely on calculation of EPC. Actually, EPC should be the same for both the RME and CT. Since *the LWG used different EPCs for the RME and CT calculations, EPA is requiring the removal of the CT evaluations for the consumption scenarios in the BHHRA."*					
2b	*"Further, reference to RME and CT in the BHHRA were not consistent with those agreed to in the Programmatic Work Plan. EPA has modified the BHHRA to reflect those agreements and adequately describe the RME and CT."*	§3.4.3, p. 25. "The fish consumption evaluation will be based on a range of fish consumption rates. Because these consumption rates will not be designated as representing either RME or CT exposures, the EPCs for tissue will not be developed specifically for RME or CT scenarios." §3.5.1.4, p. 32. "Site-specific fish consumption information is not available for the recreational fisher or high consumption non-tribal fisher scenarios. Therefore, to evaluate the potential range in consumption patterns that may exist for these receptors, 3 ingestion rates will be used to calculate intakes for adults and 3 will be used for children. For adults, the fish ingestion rates that will be used in the HHRA are 17.5 grams per day (g/day), 73 g/day, and 142 g/day. The corresponding rates that will be used for children are 7 g/day, 31 g/day, and 60 g/day. These ingestion rates are anticipated to represent average to high end ranges of fish consumption for these receptors."	There were 10 comments provided on July 16, 2010 that requested or directed revisions to text describing the fish consumption scenarios. None of those comments referenced RME or CT scenarios. For example, July 16, 2010, **comment G1** (directed change): "The draft Portland Harbor Baseline Human Health Risk Assessment (BHHRA) includes numerous statements regarding the fish consumption rates used to evaluate the risks to human health. The three primary non-tribal fish ingestion rates used in the draft BHHRA are characterized as high (17.5 grams per day [g/day]), higher (73 g/day), and highest (142 g/day). EPA disagrees with this characterization, believes them to be misleading, and believes that significantly higher ingestion rates may be appropriate to represent different local and ethnic populations that rely on fishing as part of their culture and/or as a substantial food source. As such, the three ingestion rates presented in the BHHRA should be characterized as low, moderate, and high. The rate of 17.5 g/day (equivalent to two 8-ounce meals per month) is based on the 90th percentile rate for uncooked freshwater and estuarine finfish and shellfish for individuals (consumers and non-consumers) of age 18 and over in the United States (EPA 2002b, data from USDA CSFII Study). The 90th percentile for fish consumers only from this USDA study is much higher, at 200 g/day. EPA uses the 17.5 g/day rate to approximate a fish-consuming population that does not include tribal or subsistence fishers. It is not an unreasonable rate, and should not be referred to as a high ingestion rate, but rather as a low ingestion rate. A non-tribal adult fish consumption rate of 73 g/day was used in this risk assessment based on data from the Columbia Slough. The possible uncertainties associated with the consumption rates derived from this study are appropriately discussed in the	LWG September 15, 2010 *General Responses to Directed Comments on BHHRA*: "As discussed at the September 9th meeting, ingestion rates will be presented in the revised BHHRA as the numeric rates (i.e., grams per day or meals per month) and the source of the rates will be presented, consistent with the text in the Programmatic Work Plan. Characterization or descriptors of the ingestion rate (e.g., "low", "high") will not be included in the revised BHHRA." EPA September 22, 2010 *EPA General Responses to EPA Directed BHHRA and BERA Comments*: "EPA has reviewed the September 15, 2010 letter and attachments and agrees, with clarifications, that EPA's directed comments on the BERA and BHHRA should be revised in accordance with the general framework, and that the proposed resolution described in LWG's general responses matches our understanding of the meeting outcome." Includes three unrelated clarifications.	Revised text in §3.5.1.5.3: "The fish consumption scenario included three different fish ingestion rates, as well as single species and multiple species diets of resident fish species. Study Area-specific fish consumption information is not available for the fish consumption scenarios. Therefore, to evaluate the potential range in consumption patterns that may exist, three ~~high-end~~ ingestion rates were used to calculate intakes for adults and three were used for children. EPA specified the ingestion rates used in this BHHRA. For adults, the fish ingestion rates were 17.5 grams per day (g/day), 73 g/day, and 142 g/day. These rates correspond to approximately 2 meals per month, 10 meals per month, and 19 meals per month, based on an 8-ounce serving size, every month of the year, consisting exclusively of fish caught within the Study Area. It should be noted that the current fish consumption advisory, based on PCBs, for the LWR recommends that children and expectant mothers do not eat resident fish from the Portland Harbor, and that healthy adults eat no more than one 8-ounce meal per month of resident fish from the Portland Harbor (ODHS 2007). However, it is unclear to what extent this advisory is followed by people who consume fish from the Study Area."	"No studies were located that document specific consumption rates of recreational or subsistence anglers in Portland Harbor prior to its listing as a Superfund site. Surveys conducted subsequent to the listing would not be representative of historical, baseline consumption patterns due to subsequent fish advisories and efforts to limit consumption of fish caught from the harbor. Therefore, fish consumption rates from published studies were used to describe the range of reasonably expected exposures relevant to the different populations known to occur in the Portland Harbor area. Three different rates were evaluated: 17.5 grams per day (approximately 2 eight ounce meals per month), 73 g/ day (10 eight ounce meals per month), and 142 g/day per day (19 eight ounce meals per month). The term "recreational fishers" is intended to encompass a range of the population while focusing on those who may fish on a more-or-less regular basis, and "subsistence fishers" to represent populations with high fish consumption rates, recognizing that fish are not an exclusive source of protein in their diet. Accordingly, 17.5 g/day is considered representative of a CT value for recreational fishers, and 73 g/day was selected as the RME value representing the higher-end consumption practices of recreational fishers. The consumption rate of 142 g/day represents a RME value for high fish consuming, or subsistence, fishers. No CT value was selected because the evaluations based on 17.5 g/day and 73 g/day inform the risks associated with lower consumption rates. Consumption rates for children aged 6 years and younger were calculated by assuming that their rate of fish consumption is

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			BHHRA. The BHHRA discussion and the data from the USDA study support use of a fish consumption value of 73 g/day as moderate consumption rate, not a higher consumption rate. The rate of 142 g/day used as the highest rate for non-tribal fishers in the draft BHHRA is the 99th percentile for consumers and non-consumers from the same USDA study; the consumption rate for consumers only from this study is 506 g/day. The ingestion rate of 142 g/day is used by EPA in developing Ambient Water Quality Criteria (AWQC) for consumers who obtain much of their daily protein from fish. The consumption rate of 142 g/person/day was selected in the BHHRA to represent high-frequency, non-tribal fishers, and represents an appropriate "high" ingestion rate for the Portland Harbor (PH) risk assessment." See also July 16, 2010, **comments S49, S63, S64, S93, S94, S98, S101, S138, and S140**			approximately 42 percent of an adult, based on the ratio of child-to-adult consumption rates presented in the CRITFC Fish Consumption Survey (CRITFC 1994). The corresponding rates that were used for children are 7 g/day, 31 g/day, and 60 g/day." .
3	*"There were many instances in the BHHRA where the only explanation the LWG provides for why something is done was that EPA directed or otherwise required it be done. While it may be true EPA directed changes, the LWG is fully aware of the technical basis for the direction and should have included such technical basis in the report. The LWG's failure to fully explain the basis for how the risk assessment was done is not consistent with EPA guidance nor is the report complete and transparent without it. Therefore, EPA had to modify the report to provide the rational for the directions in the text of the BHHRA for clarity and relevance for the assessment."*	This issue was not raised by EPA during development and finalization of the Programmatic Work Plan.	EPA did not provide any comments on the 2009 Draft BHHRA indicating that the rationale for EPA's directions needed to be provided. Several of the July 16, 2010 comments request or direct deletion of specific text indicating that an assumption or evaluation was directed or required by EPA. For example, **comment S125**, §7.2.3, p. 115 (directed change): Delete the following sentences: ~~*"As required by EPA Region 10, this BHHRA included exposure scenarios that are not well documented, so it is unknown to what extent exposures currently occur, if at all, within the Study Area. In addition, this BHHRA evaluated risks associated with a hypothetical future scenario, which is not anticipated to reasonably occur in the future based on current information for the Study Area. The uncertainties associated with these potential and hypothetical exposure scenarios are discussed in the following subsections."*~~ Consistent with EPA Superfund guidance, EPA and its partners chose only those scenarios that are reasonably anticipated to occur and are consistent with current statutory or regulatory requirements (e.g. designated beneficial use of the river as a source for drinking water).	LWG September 15, 2010 *General Responses to Directed Comments on BHHRA*: "The LWG disagrees with EPA's directed changes requiring the deletion of references to prior EPA direction from the draft BHHRA. As discussed at the August 20th and September 9th meetings, language stating that evaluations were done at the direction of EPA can remain in the revised BHHRA. Language implying opinion or judgment about the prudence of that direction will be removed." EPA September 22, 2010 *EPA General Responses to EPA Directed BHHRA and BERA Comments*: "EPA has reviewed the September 15, 2010 letter and attachments and agrees, with clarifications, that EPA's directed comments on the BERA and BHHRA should be revised in accordance with the general framework, and that the proposed resolution described in LWG's general responses matches our understanding of the meeting outcome." Includes three unrelated clarifications.	Revised text in §7.2.3 (now §6.2.3): "Some of the exposure scenarios evaluated in this BHHRA have limited documentation regarding the actual extent of exposure to receptors in the Portland Harbor. These scenarios were included in this BHHRA at the direction of EPA Region 10. The uncertainties associated with these scenarios are discussed in the following subsections. ~~As required by EPA Region 10, this BHHRA included exposure scenarios that are not well documented, so it is unknown to what extent exposures currently occur, if at all, within the Study Area. In addition, this BHHRA evaluated risks associated with a hypothetical future scenario, which is not anticipated to reasonably occur in the future based on current information for the Study Area. The uncertainties associated with these potential and hypothetical exposure scenarios are discussed in the following subsections.~~"	All references to EPA directing the use of specific scenarios, assumptions or evaluations in the BHHRA have been deleted. For example, the text addressed by EPA's June 16, 2010 **S125** (now §6.2.2), has been revised to read, "Some of the uncertainties associated with the exposure scenarios evaluated in the BHHRA are discussed in the following subsections."
4	*"Overall, the BHHRA did not present the process and information in a clear and*	This issue was not raised by EPA during development and finalization of the Programmatic Work Plan.	EPA did not provide any comments on the 2009 Draft BHHRA indicating that the process or information was not presented in			This is a new comment from EPA, and is reflected in extensive text revisions throughout EPA's redline/strikeout

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	transparent manner that would allow anyone outside those intimately involved in the development of this assessment to follow and understand. Thus, EPA had to extensively modify the report to make the report understandable to the general public."		a clear and transparent manner. Note EPA December 23, 2009 *Preliminary Comments on the Baseline Human Health and Ecological Risk Assessments*: "Overall, most of the procedures followed in the BHHRA and BERA are consistent with and followed the procedures agreed upon by EPA and the LWG for completing the baseline risk assessments." See also, EPA July 16, 2010 *EPA Comments on Portland Harbor draft Remedial Investigation Report*: "EPA has attempted to provide clear direction on the specific revisions that are needed to resolve the comments" on the baseline risk assessments.			edits.